Challenges in activation of remote monitoring in patients with cardiac rhythm devices during the coronavirus (COVID-19) pandemic

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Abstract: BACKGROUND Remote monitoring (RM) technology embedded in cardiac rhythm devices permits continuous monitoring of device function, and recording of selected cardiac physiological parameters and cardiac arrhythmias and may be of utmost utility during Coronavirus (COVID-19) pandemic, when in-person office visit for regular follow-up were postponed. However, patients not alredy followed-up via RM represent a challenging group of patients to be managed during the lockdown. METHODS We reviewed patient files scheduled for an outpatient visit between January 1, 2020 and May 11th, 2020 to assess the proportion of patients in whom RM activation was possible without office visit, and compared them to those scheduled for visit before the lockdown. RESULTS During COVID-19 pandemic, RM activation was feasible in a minority of patients (7.8% of patients) expected at outpatient clinic for a follow-up visit and device check-up. This was possible in a good proportion of complex implantable devices such as cardiac resynchronization therapy and implantable cardioverter defibrillator but only in 3 patients with a pacemaker the RM function could be activated during the period of restricted access to hospital. CONCLUSIONS Our experience strongly suggest to consider the systematic activation of RM function at the time of implantation or - by default programming - in all cardiac rhythm management devices.

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Short communication

Challenges in activation of remote monitoring in patients with cardiac rhythm devices during the coronavirus (COVID-19) pandemic

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ABSTRACT

Background: Remote monitoring (RM) technology embedded in cardiac rhythm devices permits continuous monitoring of device function, and recording of selected cardiac physiological parameters and cardiac arrhythmias and may be of utmost utility during Coronavirus (COVID-19) pandemic, when in-person office visit for regular follow-up were postponed. However, patients not alredy followed-up via RM represent a challenging group of patients to be managed during the lockdown.

Methods: We reviewed patient files scheduled for an outpatient visit between January 1, 2020 and May 11th, 2020 to assess the proportion of patients in whom RM activation was possible without office visit, and compared them to those scheduled for visit before the lockdown.

Results: During COVID-19 pandemic, RM activation was feasible in a minority of patients (7.8% of patients) expected at outpatient clinic for a follow-up visit and device check-up. This was possible in a good proportion of complex implantable devices such as cardiac resynchronization therapy and implantable cardioverter defibrillator but only in a minority of patients with a pacemaker the RM function could be activated during the period of restricted access to hospital.

Conclusions: Our experience strongly suggest to consider the systematic activation of RM function at the time of implantation or – by default programming - in all cardiac rhythm management devices.

1. Background

Remote monitoring (RM) technology embedded in cardiac rhythm devices permits continuous monitoring of device function, and recording of selected cardiac physiological parameters and cardiac arrhythmias. RM is associated with improved survival, and a graded relationship with the level of adherence [1]. During Coronavirus (COVID-19) pandemic [2], in-person office visit for regular follow-up were postponed and scientific societies called for massive implementation of RM in cardiac rhythm device patients [3,4]. However, patients not followed-up via RM represent a challenging group of patients to be managed. RM activation usually requires programming steps during in-office visit, registering transmitter and obtaining consent from the patients. This leaves aged patients at risk of infection in case they are seen in the hospital or at outpatient clinic [5,6], and can be time consuming in these unprecedented times of limited resource availability. On the other hand, RM initialization without the patients coming to the office or hospital is technically feasible but the RM function needs to be already activated. When the device RM function is turned ON, the patient only needs to plug in the transmitter device and follows few steps for initiating transmission. In selected device types (Boston Scientific, Abbott, Microport and Medtronic Pacemakers, Medtronic devices using BlueSync technology and last generation Microport ICD/CRT) (Fig. 1), RM is programmed by default ON thus, easily enabling activation without significant interaction by hospital personnel and patient. For other devices manufacturers (Biotronik and previous generation of Microport and Medtronic ICD or CRT), remote monitoring needs an in-person visit with the need of programming ON the device, although this function may be turned ON at the time of implant. This is not clearly recommended by international scientific societies [7,8]; thus, it is not customary in the vast majority of hospitals including ours especially for patients with pacemakers. We aimed to report the proportion of patients in whom RM was possible without office visit during the COVID-19 pandemic.

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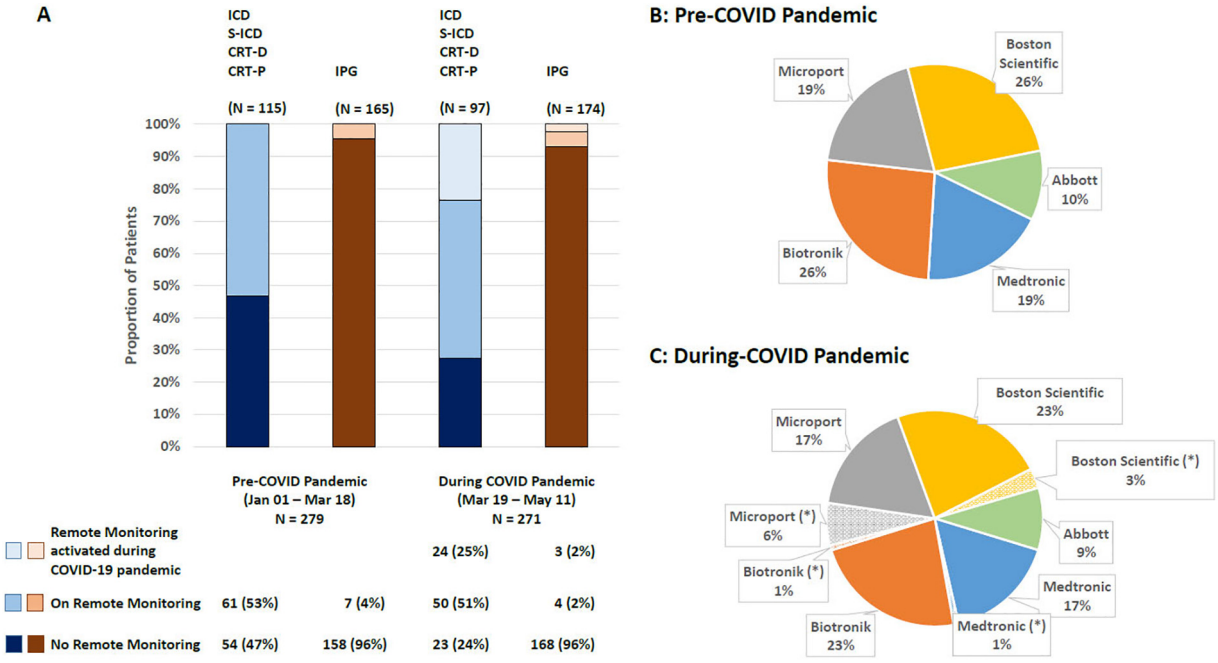

Fig. 1. Panel A shows the proportion of patients with RM before and during COVID-19 pandemic according to cardiac implantable electronic device type. Panel B and C show distribution of device manufacturers before and during COVID-19 pandemic. The asterisk indicates the proportion of patients in whom RM activation without in-person visit was feasible.

2. Methods

We reviewed patient files scheduled for an outpatient visit between January 1, 2020 and May 11th, 2020 to assess the proportion of patients in whom RM activation was possible without office visit. RM technology became available at our Institution in 2010. Before the pandemic period, for institution's policy, most of devices on RM were ICD and CRT-D; only a minority of devices (4%) were PMs, due to the lack of reimbursement and of large scientific evidence. We compared the group of patients before local authorities (Canton Ticino, Switzerland) restricted access to hospital and offices (March 18th, 2020) to those during the period of restricted access which ended on May 11th, 2020 in Canton Ticino, one of Swiss Cantons, in which RM of all implanted device (3 implanting centers) is exclusively managed by one institution (Cardiocentro Ticino), thus working as RM device hub. As indicated by scientific societies [9] patients with ICD/CRT-D have a scheduled in office visit every 6 months, and patients with PM are scheduled every year. During the pandemic, in patients with RM, we scheduled a transmission per month in patients with CRT-D/ICD and a transmission every two months in patients with IPG.

3. Results

A total of 550 patients were scheduled for in-person visit during the first 19 weeks of year 2020. The weekly and total number of patients expected at follow-up before and during the pandemic hospital outpatient clinic closure were similar (Table 1) During COVID-19 pandemic, RM activation was feasible in a minority of patients (7.8% of patients) expected at outpatient clinic for a follow-up visit and device check-up; this was possible in a good proportion of complex implantable devices such as cardiac resynchronization therapy and implantable cardioverter defibrillator of some device manufacturers (Boston Scientific, and Microport) by sending the external device directly to the patients. Only in 3 patients with a pacemaker (Fig. 1) the RM function could be activated during the period of restricted access to hospital. In a few cases of device by Medtronic (2 patients) and Biotronik (2 patients), it was possible to active RM because they the RM function was already activated at implantation time (Fig. 1). A total of 15 patients without RM complained symptoms during the COVID pandemic (3 syncope; 11 palpitations; 1 dizziness), 2 patients reported an acoustic alarm and 2 patients experienced ICD interventions requiring hospital admission. These cases could have been managed by RM to rule out arrhythmias or devices malfunction.

Table 1
Characteristics of patients expected at follow-up before and during the pandemic hospital out-patient clinic closure.

	Patients expected at follow-up visit Jan 01, 2020 - Mar 18, 2020 (n = 279)	Patients expected at follow-up visit Mar 19, 2020 - May 11, 2020 (n = 271)
Age – yr	72	73
Male sex – no (%)	212 (75.8%)	206 (76.0%)
Coronary artery disease – no. (%)	135 (48%)	141 (52%)
Atrial fibrillation – no. (%)	89 (32%)	97 (36%)
Cardiac Implantable Electronic Device type – no. (%)		
- Implantable cardioverter-defibrillator	55 (20%)	36 (14%)
- Cardiac resynchronization therapy	60 (21%)	61 (23%)
- Implantable pulse generator	165 (59%)	174 (64%)
Remote monitoring refused by patient – no. (%)	3 (1.1%)	2 (0.7%)

4. Discussion

Our experience strongly suggest to consider the systematic activation of RM function at the time of implantation or – by default programming - in all cardiac rhythm management devices. This shall allow an easy activation of RM function without major physical interaction with hospital nurse or technician especially when access to outpatient clinic is critically restricted as during pandemic and/or there is a

shortage in human resources. Cardiac rhythm device patients may be considered at particular risk of COVID-19 infection because of their average age (60 to 80 years old), the cardiovascular risk profile and the significant burden of co-morbidities such as atrial fibrillation, diabetes, peripheral vascular artery disease, chronic obstructive pulmonary disease, etc. Although the replacement of in-person visit by a massive adoption of RM has been advocated by international scientific societies, the implementation has been challenging due to technical limitations experienced in providing the patients with hardware required for transmission. At the time of pandemic breakout only 3 out of 5 device manufacturers enables RM activation without the patients coming to the office or hospital. On the other hand, several pacemaker patients in whom RM activation was technical feasible were very reluctant in being remotely monitored. This situation contrasted the acceptance of RM by patients with more complex devices in whom RM was easily active in a large proportion of patients. The precise reason for the difference is unknown but may be due to patient's age or perceived benefit by the patients and caregivers of the value of RM in pacemaker patients. Alternatively as shown by Varma et al. [1], the degree of RM use in USA showed wide geographic variability especially in rural area or in areas with challenging socio-economic conditions. In conclusions, recommendation by international scientific societies about systematic RM activation function in all cardiac rhythm device patients at the time of implantation shall be explicitly formulated. Furthermore possible amendment of the restriction imposed by General Data Protection Regulation, which prohibits the direct shipment of transmitter to the patient's home by manufacturers shall be considered. Finally, one of the most important reported barriers to the implementation of RM is the lack of reimbursement and the increased institutional workload [10]. Therefore, further efforts to improve RM drivers (reimbursement, patient's awareness of a need for RM and related benefits, and avoidance of in-office follow-ups during a pandemic) are strongly warranted.

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Credit authorship contribution statement

Angelo Auricchio: Project administration, Formal analysis, Conceptualization, Methodology, Resources, Visualization, Writing - original draft; **Giulio Conte**: Data curation, Software, Writing - original draft; **Andrea Demarchi**: Data curation, Investigation, Writing - original draft, Writing - review & editing; **Enrico Baldi**: Writing - review & editing; **Tardu Özkartal**Writing - review & editing; **Francois Regoli**: Supervision; **Tiziano Moccetti**: Supervision, Validation.

Declaration of Competing Interest

A.A is a consultant to Boston Scientific, Cairdac, Corvia, Microport CRM, EPD Philips, Radcliffe Publisher. He received speaker fees from Boston Scientific, Medtronic, and Microport. He participates in clinical trials sponsored by Boston Scientific, Medtronic, EPD-Philips. He has intellectual properties with Boston Scientific, Biosense Webster, and Microport CRM. G.C has received a research grant (PZ00P3_180055) from the Swiss National Science Foundation (SNSF) F.R has received speaker fees from Medtronic, consulting fees from Daichi Sankyo, and travel costs by Bayer.

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